K 110419

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JUL 28 2011

510(k) Summary

Contact:	Kimberly Lane Sr. Regulatory Affairs Specialist Stryker Spine 2 Pearl Court Allendale, NJ 07401
Date Prepared:	July 22, 2011
Device Trade Name:	AVS® ARIA Neuromonitoring Probe and AVS® ARIA Probe Dilators
Submitter:	Stryker Spine 2 Pearl Court Allendale, NJ 07430
Manufacturer:	Stryker Spine ZI de Marticot, 33610 Cestas - FRANCE
Common Name:	Electrode needle
Classification:	21 CFR § 882.1350
Class:	II
Product Code:	GXZ

Indications For Use:
The AVS® ARIA Neuromonitoring Probe and AVS® ARIA Probe Dilators are indicated for use during surgery of the spine to deliver an electrical stimulus to the tissues and nerves at the operative site to assist in locating those nerves at risk during the surgical procedure.

Device Description:

The AVS® ARIA Neuromonitoring Probe (NM Probe) and AVS® ARIA Probe Dilators are used as instruments to deliver electrical stimulation to tissue during intraoperative neurological monitoring. The NM Probe and probe dilators are available in monopolar configuration. These are made from stainless steel (NM Probe) insulated with either polytetrafluoroethylene or polyphenylsulfone (dilator tubes). The NM probe has a male 1.5mm DIN connector. The components are provided clean to users for sterilization prior to use. The components are not intended for cleaning, reprocessing, or reuse.

Reference Number	Device Name
48755006	NM Probe/Guide Wire
48755001	Dilator 1 – 6.4mm
48755002	Probe Dilator 2, NM – 14.4mm
48755003	Probe Dilator 3, NM – 22.5mm

The NM Probe and probe dilators are provided by Stryker Spine non-sterile and must be sterilized by the end user prior to use and subsequently disposed of after use in a single case. These devices are not labeled non-pyrogenic.

Predicate Device(s):
The AVS® ARIA Neuromonitoring Probe and AVS® ARIA Probe Dilators were shown to be substantially equivalent to the below previously cleared devices and have the same indications for use, design, function, and materials used.

510(k)	Company Name	Device Name
K090838	Axon Systems, Inc.	XPAK & XPAK II
K062996	Axon Systems, Inc.	Disposable Stimulator Probes
K850107	Carefusion (Nicolet)	Probes

Performance Standards:
The device was tested in accordance with IEC 60601-1-2: 2007 and the test results indicate that the AVS® ARIA Neuromonitoring Probe and AVS® ARIA Probe Dilators are substantially equivalent to predicate devices. All stainless steel components, comply with ASTM F899 and NF S94-090 and all PTFE components comply with ASTM D4895. All devices have been validated, in both gravity and pre-vacuum, in their surgical case set for a Sterility Assurance Level (SAL) of 10^{-6} according to AAMI ST 79: 2010, AAMI A1:2010, AAMI TIR 12:2010, and ISO 17665-1: 2006. The steam sterilization parameters are:

Prevacuum (Porous Load) steam sterilization autoclave:
- Temperature: 132°C (270°F)
- Exposure Time: 4 Minutes
- Dry Time: 20 Minutes

Gravity Displacement steam sterilization autoclave:
- Temperature: 132°C (270°F)
- Exposure Time: 15 Minutes
- Dry time: 30min.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Stryker Spine
c/o Ms. Tiffani Rogers
Regulatory Affairs Manager
2 Pearl Court
Allendale, NJ 07401

JUL 28 2011

Re: K110419
Trade/Device Name: AVS ARIA Neuromonitoring Probe and AVS ARIA Probe Dilators
Regulation Number: 21 CFR 882.1350
Regulation Name: Electrode Needle
Regulatory Class: Class II
Product Code: GXZ
Dated: July 14, 2011
Received: July 15, 2011

Dear Ms. Rogers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110419

Device Name: **AVS® ARIA Neuromonitoring Probe and AVS® ARIA Probe Dilators**

The AVS® ARIA Neuromonitoring Probe and AVS® ARIA Probe Dilators are indicated for use during surgery of the spine to deliver an electrical stimulus to the tissues and nerves at the operative site to assist in locating those nerves at risk during the surgical procedure.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K110419

Prescription Use X
(Per 21 CFR 801.109)